IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
SOUTHERN DIVISION
No. 7:22-CV-73-M

CENTER FOR ENVIRONMENTAL HEALTH, ET AL., PLAINTIFFS v. MICHAEL S. REGAN, ADMINISTRATOR OF THE U.S. ENVIRONMENTAL PROTECTION AGENCY, AND THE U.S. ENVIRONMENTAL PROTECTION AGENCY, DEFENDANTS	**PLAINTIFFS' SUPPLEMENTAL REPLY MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS**

Pursuant to the Court's January 23, 2023 Order, plaintiffs' hereby reply to defendants' February 1, 2023 opening memorandum.

I. Did Plaintiffs File One or Several Petitions?

Plaintiffs submitted one section 21 petition to EPA on October 13, 2020. However, like many section 21 petitions,[1] it contained numerous requests for relief, not one request that EPA could only grant or deny. EPA claims that the petition "broadly characterizes the risk associated with the 54 identified substances" and makes no "claim that each substance has a risk distinct from one another." EPA Feb. 1 Memo, at 2. This is untrue. The petition differentiated among the 54

[1] See description of petitions filed since 2007 at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-21#petition18.

PFAS proposed for testing, separately describing the evidence of exposure and release for each PFAS. Petition, Attachment 2. Based this analysis, the petition proposed a separate tier of substances with substantial human exposure that would undergo more comprehensive studies in recognition of their greater potential for long-term health effects.[2] The petition also requested a wide range of studies designed to address different health and environmental end-points and develop data serving different purposes.[3]

Thus, EPA was faced not with a binary choice between granting and denying the petition but with a large menu of options and outcomes. It had to decide between testing a small number of PFAS or all 54 substances; adopting the comprehensive testing program in the petition or picking a smaller subset of studies; and issuing one comprehensive test order or several narrower orders. EPA's petition response recognized the multiplicity of requests in the petition. Instead of treating the 54 PFAS as interchangeable, it assigned them to 12 PFAS subclasses, selected 7 of the PFAS for testing, and concluded that the rest did not warrant testing for a variety of reasons (including that 15 substances did not meet its PFAS definition). Pet. Resp. at 2-3, 14-17. Similarly, it addressed the proposed studies individually and explained why most of them were unnecessary. Id. at 17-24. The end result was that EPA decided to require testing on 7 of the 54 PFAS but not the other 47 and to mandate some studies but reject several others.

[2] 14 PFAS were assigned to this higher tier on the basis of evidence of their presence in human blood, drinking water and/or food. Petition, at 12-16. The petition proposed multigeneration or extended one-generation and 2-year rodent carcinogenicity studies on these 14 substances but not on the remaining 40 PFAS. Id. at Table 4-B.

[3] These include an epidemiology study examining patterns of disease and exposure within the Cape Fear population; rodent toxicology studies on the mixtures of PFAS found in human blood and drinking water to determine whether exposure to multiple PFAS is more harmful than exposure to individual substances; half-life studies to determine how long different PFAS are retained in the human body; physical-chemical properties studies and toxicokinetic studies to examine the uptake and distribution of PFAS in the body; ecotoxicity and fate and transport studies to understand how the PFAS behave in the environment; and development of analytical methods. Id. at Table 4.

Rather than granting the entire petition, EPA thus granted it in part and denied it in part. On the one prior occasion when it accepted some petition requests but rejected others, EPA similarly said the petition had been "granted in part and denied in part." 78 Fed. Reg. 41768 (July 11, 2013).[4] Indeed, the principal case defendants cite recognizes that a single petition can present multiple requests for relief and that acting on one request is not equivalent to responding to the entire petition. *Center for Biological Diversity v. Jackson*, 815 F. Supp. 2d 85 (D.D.C.2011).

Section 21(b)(4)(A) makes a judicial remedy available "[i]f the Administrator denies a petition." It makes no difference whether the denial is partial or total. To grant a motion to dismiss where the allegations in plaintiffs' Amended Complaint demonstrate that EPA denied most of their requests would negate the *de novo* judicial remedy that Congress gave unsuccessful petitioners. Since large portions of the petition were rejected, plaintiffs are entitled to ask the Court "to compel the Administrator to initiate a [] proceeding as requested in the petition" under section 21(b)(4)(A).

II. Can EPA's Categorical Approach be Upheld on a Motion to Dismiss?

EPA argues that its petition response "comports with statutory requirements that express a preference for a 'category-based' approach." EPA Mem. at 4. However, while Congress may have given EPA authority to require testing on categories, it did not mandate this approach. For example, the 2020 National Defense Authorization Act ("NDAA") requires EPA to develop a testing process for PFAS "*substances or classes of substance*" based on their "potential for human exposure" and "potential toxicity" and "information available." 15 U.S.C. §8962 (emphasis added). TSCA section 4(h)(1)(B)(ii) identifies "the grouping of 2 or more chemical substances into scientifically

[4] On the two occasions where EPA "granted" petitions since 2007, it agreed to all the relief requested by the petition. See https://www.epa.gov/sites/default/files/2015-10/documents/owens.cadmium.response.8.30.10.pdf (granting petition for TSCA section 8(d) reporting requirements on cadmium and cadmium products); https://www.epa.gov/sites/default/files/2015-10/documents/owens.cadmium.response.8.30.10.pdf (granting petition for TSCA section 6 rule prohibiting lead wheel balancing weights).

appropriate categories" as one way to reduce testing on vertebrate animals but stipulates that testing of a representative chemical must "provide *scientifically valid and useful information* on other chemical substances in the category" (emphasis added). While EPA's petition response (at 10) cites a "long history" of testing on categories, the testing activities it describes are those of the multi-national Organisation for Economic Cooperation and Development, not the TSCA section 4 testing program. EPA does not identify a single previous TSCA test rule or order intended to develop data on a large chemical category, much less one with over 6500 component chemicals.

Ultimately, the issue in this case is not whether EPA has the authority to use appropriate categories for PFAS testing but whether doing so here will "provide scientifically valid and useful information" that fulfills the objective of plaintiffs' petition -- to inform an understanding of how the particular PFAS in the blood and drinking water of Cape Fear residents have affected their health. While PFAS as a class may "present an unreasonable risk of injury" because many PFAS exhibit common modes of toxicity, this does not mean the health effects of all PFAS are identical or that their harmful properties are independent of the levels and pathways of exposure in a particular community or the unique combination of PFAS in residents' blood and drinking water. For this very reason, plaintiffs' petition proposed epidemiology and mixture studies that would examine the causal relationship between adverse health outcomes and patterns and sources of exposure in the Cape Fear basin. However, in rejecting these and other requested studies, EPA failed to explain how the limited testing it agreed to require will elucidate the unique health consequences of PFAS exposure by Cape Fear communities. Without connecting these studies to petitioners' core goals and concerns, it is inexplicable how EPA's response could be characterized as fully "granting" the petition.

As these considerations suggest, whether limited studies on substances "representative" of

the PFAS category will yield "scientifically valid and useful information" on risks to Cape Fear residents is a disputed issue of fact, not an abstract question of law or policy. It should t be resolved not on a motion to dismiss but in the *de novo* proceeding afforded under section 21(b)(4)(B).

III. Is EPA's "Proceeding" in Response to the Petition Relevant to the Motion to Dismiss?

Defendants concede that "whether the intended proceedings that EPA described in its response to Plaintiffs' petition are 'appropriate' is beyond this Court's scope of review." EPA Mem. at 7. Thus, if this case is dismissed, plaintiffs will lack a vehicle to challenge the sufficiency of EPA's actions in fulfilling the goals of their petition. The Court should deny EPA's motion and give plaintiffs the opportunity to make their case on the merits that Congress provided.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 8th day of February 2023, a true and correct copy of the foregoing Supplemental Reply Memorandum was filed electronically with the Clerk of the Court using CM/ECF. I also certify that the foregoing is being served on all counsel of record via Notice of Electronic Filing generated by CM/ECF.

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